

REMARKS

In the Office Action, the Examiner indicated that claims 76-78 are allowable. Claims 143-148, 151-160, 162-164 and 169-176 are allowed.

Also in the Office Action, claims 71-75, 79-142, 149, 150, 161, 165-168 and 177-186 are rejected. The Applicant submits that the amendments to the claims overcome the rejection of the claims or the rejections are traversed by argument below. No new matter has been added. The Applicant submits that the claims are in condition for allowance and requests favorable consideration.

In the Claims, please amend claims 71, 72, 74, 109, and 117. The claims have been amended to remove reference to "prevention and/or". In addition, the claims have been amended to replace "cancer" with "reducing the growth of cancer cells and/or inhibiting the metastasis of metastatic neoplasms". Support for this amendment can be found in the original disclosure, for instance on page 6. [0075]. Since there is support for the amendments to the claims, no new matter has been added. Claims 89-90, 110 and 149 are all amended to correctly recite a trademark in the claim. No new matter has been added as a result of this amendment. Claims 177-186 (previously claims 178-187) have been renumbered to correct an error in numbering and in addition, the dependencies have likewise been amended. No new matter has been added. The amendments to the claims can be viewed in the Amendments section of this paper in the Listing of claims beginning on page 3.

Also in the Claims, please newly add claims 187 to 225. These claims are directed to a method of preventing the conditions listed in the claims. The claims are based on claims 71-186. No new matter has been added. These new claims can also be viewed in the Amendments section of this paper in the Listing of claims beginning on page 3.

In the specification, please amend the specification as shown in the Amendments section of this paper beginning on page 3 wherein the recitation of the trademarked product has been corrected so that it is in compliance with the Rules. No new matter has been added.

In the Office Action, the Examiner indicated that claims 71-74, 79, 81, 83, 85, 87, 89, 91, 93, 95, 97, 99, 101, 103, 105, 107, 109-121, 123, 124, 126, 127, 129, 130-134, 136, and 138-141 are rejected under 35 U.S.C. §112, first paragraph. The Examiner asserts that the claims are not enabling for the treatment/prevention of "cancer". The Applicant has amended the claims to replace the term "cancer" with "reducing the growth of cancer cells and/or inhibiting the metastasis of metastatic neoplasms". The Applicant submits that this amendment provides more specificity and clarity to the terms, and therefore, overcomes the rejection. Furthermore, the Background section of the Application discloses the beneficial features of non β -oxidizable fatty acid entities as they relate to reducing the growth of cancer cells and/or inhibiting the metastasis of metastatic neoplasms. (Application [0002]-[0003].) As disclosed throughout the Application, the addition of a protein material gives a potentiated or synergistic effect, although the qualitative biological effects are similar as for the administration of the non β -oxidizable fatty acid entities alone.

The Examiner also rejected the claims based on the term "preventing" asserting that the application is not enabled for preventing the conditions claimed. The Applicant respectfully disagrees and respectfully traverses this rejection. Although the Applicant has removed the term from claims 71-186, new claims 187-225 are directed to "preventing" these conditions, and therefore, the discussion herein is relevant to these new claims. This rejection as to claims 71-186 is, however, rendered moot in light of the amendment, and therefore, the Applicant respectfully requests that the Examiner withdraw the rejection that is asserted.

The specification provides clear guidance and working examples that enable a person skilled in the art to make and use the claimed invention for both treating and preventing various of the conditions listed in the claims. For instance, Example 2 provides results showing that the composition of the present invention effectively decreases the levels of cholesterol, triglycerides and phospholipids in the plasma. Example 1 provides results showing that the composition of the present invention is effective in increasing acyl-CoA and decreasing plasma phospholipids. These effects are further discussed in the specification on page 4[0060] to page 5 [0062]. Clearly the composition of the present invention is effective in lowering cholesterol, triglycerides and phospholipids in plasma.

Moreover, it was determined that the body lipid level is lower in diets including compositions and method of the present invention. (Application p. 5 [0067].) It is well known in the art by significantly that lowering body lipid levels the methods and composition of the present invention could reduce health problems such as stenosis, arteriosclerosis coronary heart disease, thrombosis, myocardial infarction, stroke, and fatty liver.

These results also illustrate that the compositions of the present invention can be used to prevent and treat insulin resistance and related diseases. In fact, the compositions of the present invention completely prevent high-fat diet induced insulin resistance and adiposity, and reduce adiposity, hyperglycaemia and insulin sensitivity in obese rats. (Application p. 5 [0071].) Other features of these compositions include preventing and treating elevated blood pressure, increased lipid and cholesterol levels, endothelial dysfunction, procoagulant state, polycystic ovary syndrome and the metabolic syndrome. (Application p. 5-6 [0071].)

In addition, the compositions and methods of the present invention reduce proliferation of many cancer cell lines. (Application p. 6 [0075].) The reduced proliferation is related to the reduction in triacylglycerol levels. For instance, soy

protein improves non β -oxidizable fatty acid entities' ability to lower triacylglycerol levels thereby improving the anti-proliferative effects. Clearly, the protein and non β -oxidizable fatty acid entities together provide an improved cancer prevention and treatment of primary and secondary neoplasms, the growth of tumours, invasion of a primary tumour into connective tissue and formation of secondary tumours.

(Application p. 6 [0075].)

The Applicant submits, therefore that a person of skill in the art would understand from the disclosure that the methods of the present invention using a protein and non β -oxidizable fatty acid entity together are particularly suited for preventing the onset of, and lowering the risks for, the claimed diseases. As the Examiner noted, the Office does not require that the presence of working examples be present in the disclosure of the invention, however, such is the case herein.

The Applicant respectfully submits that the Application fully enables a person of skill in the art to make and use the invention commensurate with the scope of the claims. The Applicant further respectfully requests that the Examiner withdraw this ground of rejection as to claims 71-74, 79, 81, 83, 85, 87, 89, 91, 93, 95, 97, 99, 101, 103, 105, 107, 109-121, 123, 124, 126, 127, 129, 130-134, 136, and 138-141 because, as suggested by the Examiner, the Applicant has deleted preventing from the claims, but further submits that the new claims 187-225 are fully enabled, as discussed extensively herein.

On page 4 of the office Action, the Examiner also rejected claims 75 and 77 under 35 U.S.C. §112, second paragraph for being indefinite. The Applicant respectfully submits that with regard to the phrase "improving the total lipid composition of an animal" a person of skill in the art would understand that ideally an animal's total lipid composition will fall within a particular range and that "improving" the composition will allow the animal's "total lipid composition" to more closely fall within the range. A person of skill in the art would understand the terms objected to,

therefore. The Applicant respectfully requests that the rejection as to claims 75 and dependant claims be withdrawn.

The Examiner also rejected claims 90, 110, and 149 for not correctly identifying a trademarked product along with the generic term. The Applicant has amended the claims and also amended claim 89 to correct for this error. The Applicant submits that the amendment overcomes the rejection and respectfully requests that the Examiner withdraw this rejection as to these claims.

CONCLUSION

The Applicant believes that this response is responsive to all points raised in the Office Action dated April 22, 2009. The Applicant respectfully contends that all conditions of patentability are met in the pending claims and requests that the amendments be entered into the record. The Applicant respectfully submits that this Application should be in condition for allowance and respectfully requests favorable consideration.

Respectfully Submitted,

Zareefa B. Flener, Pat. Reg. No. 52,896

8/17/2009
Ladas & Parry, LLP
224 South Michigan Avenue
16th Floor
Chicago, IL 60604
312/427-1300 x 229
312/427-6668 (fax)